



(19)

Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 0 793 457 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
31.10.2001 Bulletin 2001/44

(51) Int Cl.⁷: A61F 2/01, A61F 2/04
// A61B17/12

(21) Application number: 95915819.7

(86) International application number:
PCT/DK95/00147

(22) Date of filing: 06.04.1995

(87) International publication number:
WO 95/27448 (19.10.1995 Gazette 1995/45)

(54) A MEDICAL ARTICLE FOR IMPLANTATION INTO THE VASCULAR SYSTEM OF A PATIENT

EINE MEDIZINISCHE VORRICHTUNG ZUR IMPLANTATION IN DAS GEFÄSSSYSTEM EINES
PATIENTEN

DISPOSITIF MEDICAL DESTINE A ETRE IMPLANTE DANS LE SYSTEME VASCULAIRE D'UN
PATIENT

(84) Designated Contracting States:
DE FR GB

• KORSHOK, Alexandre Pavlovich
Moskovskaya obl., Moscow, 140070 (RU)

(30) Priority: 06.04.1994 RU 94012016
19.04.1994 RU 94014593

(74) Representative: Raffnsöe, Knud Rosenstand et al
Internationalt Patent-Bureau,
23 Höje Taastrup Boulevard
2630 Taastrup (DK)

(43) Date of publication of application:
10.09.1997 Bulletin 1997/37

(56) References cited:
EP-A- 0 587 197 WO-A-93/17636
WO-A-94/12136 US-A- 5 064 435

(73) Proprietor: WILLIAM COOK EUROPE ApS
4632 Bjaeverskov (DK)

(72) Inventors:
• KAVTELADZE, Zaza Alexandrovich
Moscow, 117330 (RU)

EP 0 793 457 B1

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] A medical article for implantation into the vascular system of a patient.

[0002] The invention relates to medical articles in the form of filters or occlusion devices for implantation into the vascular system of a patient, comprising a self expanding body shaped substantially into the form of a body of revolution, the surface of which is defined by wire members forming cells of a generally polygonal shape over at least a part of said surface.

[0003] Medical implantation articles to which the invention pertains have found wide-spread use in percutaneous vascular and cardiac surgery and comprise in particular intravenous filter devices for the capture of thrombi in major veins such as the lower caval vein and occlusion devices for permanent or temporary obturation of a vessel lumen or permanent occlusion of defects in vascular walls such as an ASD in the atrial septum, a PDA defect or other defects in vascular walls such as the inlet of an exfoliative aneurism of the aorta or a puncture hole in connection with angiographic investigation.

[0004] Intravenous filters for capture of thrombi have become known in many different configurations and shapes.

[0005] FR-A-2567407 discloses an umbrella-type filter comprising a number of radial legs interconnected at their ends by a semi-spherical filter membrane permeable to the blood flow.

[0006] This prior art device requires a comparatively large diameter delivery system involving a considerable risk for traumatization of the femoral or subclavian veins used for percutaneous introduction. Correct localization in the caval vein is rather difficult and unreliable and a further drawback follows from the impossibility of withdrawing the filter in cases where such withdrawal is dictated by a clinical indication.

[0007] From Radiology, 1985, 156, pages 315 to 320 a filter in the form of the body of revolution made from wire members forming a cellular surface is known which device corresponds to the preamble of claim 1. This prior art device suffers from the drawback that captured thrombi will tend to collect in the peripheral or parietal zone of the filter, whereby the efficiency of operation is impaired. Also for this prior art filter a considerable risk for traumatization of vessels during introduction prevails and it is not possible to withdraw the filter.

[0008] Also medical articles of the kind referred to for occlusion of vessels or holes in vascular walls have become known in different configurations and shapes.

[0009] From Ann.Radiology, 1981, vol. 24, no.5, pages 396 to 399 a vessel occlusion device is known having the shape of a spring spiral. With this device it has turned out to be difficult and complicated to obtain full and effective closing of a vessel lumen and the device suffers moreover from the drawback of a significant risk of displacement from the site of implantation due to blood flow or pulsation of vascular walls.

[0010] A prior art occlusion device known from SU inventors certificate No. 810246 comprises a body of revolution formed by an inflated balloon with a catheter. For this device non-uniform inflation of the balloon will result in insufficient sealing of the body against the vascular walls adjoining the duct to be closed and the occlusion will be of a rather poor quality and ineffective.

[0011] Further prior art occlusion devices for sealing cardiovascular defects comprise the shunt defect closure devices disclosed in US-A- 3874388 and 4007743. Both of these prior art devices comprise a pair of umbrella-like elements, which only after localization at the site of the defect are locked together in face to face relationship to close the defect from opposite sides.

[0012] In an article "Non-surgical closure of patent ductus arteriosus: Clinical Application of the Rashkind PDA occluder system", circulation 75 No. 3, March 1987 an occluder system is described comprising two polyurethane discs mounted on two opposing umbrella-like three-armed spring assemblies. Whereas the need for assembling the two assemblies after installation has in this case been avoided this has been obtained at the expense of a rather complicated delivery system and procedure.

[0013] A similar drawback in addition to a rather complicated structure of the occlusion device itself prevail with a prior art ASD and PDA occluder device dissolved in international patent application WO 93/10714.

[0014] An occlusion device as specified in the preamble of claim 8 is known from document WO 93/17636.

[0015] On the background of the prior art described above it is the object of the invention to provide medical articles of the kind defined for use as intravenous filter devices for arrangement in a major vein such as the lower caval vein or as supporting structures of occlusion devices for closing a vessel lumen or defects in vascular walls as mentioned above which do not suffer from the above-mentioned drawbacks of the prior art.

[0016] According to a first aspect of the invention, this object is achieved by providing a medical filter for intravenous implantation into a patient for the capture of thrombi, comprising a self expanding body shaped substantially into the form of a body of revolution, the surface of which is defined by wire members forming cells of a generally polygonal shape over at least a part of said surface, which is characterized in that said body of revolution has a diameter increasing continuously in an axial direction of the body from one end forming an apex towards the opposite end forming a base.

[0017] Such an intravenous filter will be arranged in the actual vein with an orientation of the body of revolution such that the apical end thereof will be directed downstream of the blood flow. Thereby, the thrombotic masses will be collected in the center of the lumen of the vein so that the filtration efficiency is enhanced. Correct localization of such a filter device may be secured with great reliability by dimensioning the diameter of the base of the body of revolution to be larger than that of

the vessel, whereby also an increased versatility is achieved in the sense that for a specific vein such as the lower caval vein one and the same filter size can be used with any possible diameter of the vessel.

[0018] According to a preferred embodiment the body of revolution of the medical filter of the invention is defined by a generatrix forming a n-th order curve according to the formula

$$y = Ax^n$$

where for a given point on the surface of the body x is the radius in the radial plane including said point, y is the distance from said radial plane to a plane parallel thereto including the geometrical apex, A is a constant and $n \geq 1$. Thereby the general shape of the body of revolution may vary from a conical to a more or less pronounced parabolic shape of varying slope as determined by the constant A.

[0019] When the medical filter of the invention is intended for permanent implantation a reliable localization of the article may be further secured in a manner known per se by the provision of anchoring members for fixing the article to vascular walls at the circumference of the base of the body of revolution.

[0020] Due to the shape of the medical filter a further advantageous possibility of withdrawing the article, if this is required or recommended by a clinical indication, may be obtained by providing the medical filter with wire members extending substantially diametrically across the base of the body of revolution and connected with each other at the centre to function as extraction members, which can be engaged by a hook-shaped trapping wire introduced by means of a retraction catheter.

[0021] According to a second aspect of the invention there is provided a medical occlusion device for implantation into the vascular system of a patient for closing a vessel lumen or defects in a vascular wall, comprising a self expanding body shaped substantially into the form of a body of revolution, the surface of which is defined by wire members forming cells of a generally polygonal shape over at least a part of the said surface is characterized in that said body of revolution has a diameter increasing continuously in an axial direction of the body from one end forming an apex towards the opposite end forming a base, and that a separate relatively flat disc or umbrella shaped, elastic membrane of a blood impermeable material is connected with said one end of said body of revolution and is coaxially therewith, said membrane having a diameter (d_2) exceeding the maximum diameter (d_1) at the base of said body.

[0022] Such a membrane may preferably be connected with the apical end of the body of revolution through a flexible link allowing the occluder device including the membrane and the body of revolution to be accommodated and introduced into a vessel by means of a relatively simple introducer catheter with a small external

diameter without any need of assembling separate components after localization of the article at the site of installation.

[0023] Due to this design the medical occlusion device of the invention will secure reliable and complete obturation of a vessel lumen and provide safe occlusion of defects in vascular walls of any geometry and size and in any anatomic zone of the body.

[0024] For both of the above-mentioned aspects of the invention the medical filter or occlusion device may advantageously comprise two bodies of revolution joined at their apices.

[0025] In the following the invention will be further explained with reference to the accompanying drawings in which

fig. 1 is a perspective view of a first embodiment of a medical article according to the invention serving as an intravenous filter device;

fig. 2 is a graphic representation by way of example of some possible contours of a body of revolution in a medical article according to the invention;

figs. 3 to 5 illustrate a second embodiment of the medical article according to the invention serving as an occlusion device, in a perspective view, a side view and an end view, respectively;

figs. 6 and 7 shows alternative embodiment serving as occlusion devices for defects in vascular walls;

fig. 8 illustrates the function of the embodiment shown in fig. 6 and 7 to close socalled ASD and PDA defects in the atrial septum and between the pulmonary arteria and the aorta,respectively;

fig. 9 is a side view of a third embodiment of the medical article of- the invention; and

fig. 10 illustrates application of the embodiment of fig. 9 for complete occlusion of a lower part of the spermatic venous system.

[0026] The intravenous filter shown in fig. 1 comprises two coaxial interconnected bodies of revolution 1 and 2 each defined by wire members 3 forming cells of a general rhombic shape over at least part of the surface of the body of revolution.

[0027] According to the invention, each of the bodies of revolution 1 and 2, which are of the same general shape, has a diameter increasing continuously in the axial direction from an apical end 4 towards the opposite end of the respective body whlch forms a base 5.

[0028] In the illustrated embodiment each of the bodies of revolution 1 and 2 is defined by a generatrix 6 forming a socalled n-th order curve as further illustrated in fig. 2. Mathematically this means that the generatrix 6 may be defined by the formula

$$y = Ax^n$$

where for given point on the surface of the body of rev-

olution x will represent the radius in the radial plane including said point, whereas y will represent the distance of said radial plane from a plane parallel thereto and including the geometrical apex 4 where the two bodies of revolution 1 and 2 are joining each other; A is a constant the magnitude of which will depend of the actual application and may typically be within the range $0,2 \leq A \leq 1$. For the intravenous filter embodiment shown in fig. 1 A will typically be equal or close to 1.

[0029] Fig. 2 illustrates for $A=1$ the shape of the generatrix curve x for values of the power n ranging from $n=1$ (straight line) to $n=3$.

[0030] To achieve the object of collecting captured thrombi in the center region of each of bodies 1 and 2 the power factor n may be equal to $n = 1$, whereby the body of revolution will take a generally conical form or it may be within the range

$$1 < n \leq 2$$

whereby the body of revolution will assume a more or less pronounced parabolic shape.

[0031] For the purpose of reliably fixing of the filter at a site of installation in a vein such as the lower caval vein anchoring members 7 may be provided along the circumference of the base 5.

[0032] As a special feature the filter may be provided with wire members 8 extending diametrically across the base 5 of one or both of the bodies of revolution 1 and 2 and being secured to one another at the centre of the base to function as extraction members engageable by a hook-shaped trapping wire introduced into the vein by means of a retraction catheter, not shown.

[0033] Due to the cellular surface of each of the bodies of revolution 1 and 2 and the geometrical shape thereof as explained above the entire filter composed of the two bodies of revolution may be stretched in the direction of its axis and arranged in the distal end of a hollow radioopaque introduction catheter of a small external diameter, e.g. 2.5 mm, which may be introduced percutaneously into the vascular system of a patient through a paracentetic puncture in a femoral or subclavian vein.

[0034] Such a small diameter introduction catheter will cause minimum traumatization of the walls of the vein through which the catheter with the filter is introduced.

[0035] At the desired site of implantation, such as in the lower caval vein, the filter is ejected from the introduction catheter by means of a pushing member slidably arranged inside the catheter and, by dimensioning the diameter of the base of each of the bodies of revolution 1 and 2 to be larger than the diameter of the vein or other vessel, reliable localization of the filter may be obtained also in case of temporary implantation where anchoring members are not used.

[0036] For permanent installations an even more re-

liable localization may be obtained by means of the anchoring members 7 provided at the circumference of the base of at least one of the bodies of revolution.

[0037] In the illustrated embodiment of the filter with 5 two slightly parabolic bodies of revolution 1 and 2 one of these bodies will form an active filter part having its apex oriented downstream with respect to the blood flow whereby thrombotic masses will be collected at the apex and thus in the center of the lumen of the vein in which 10 the filter is arranged. In the peripheral parts of the lumen a substantially free flow of blood will be ensured. Thereby, the risk of obturation of the vein lumen by thrombotic masses will be significantly reduced.

[0038] The filter may also be made of a single body 15 of revolution of a general shape as outlined above.

[0039] In figs. 3 to 5 another embodiment of the medical article of the invention is illustrated which is intended to function as a vessel occlusion device. Also in this embodiment the article is composed of two bodies of revolution 10 and 11 each of which has a general shape as described above and is defined by wire members 12 forming substantially hexagonal cells over at least a part of the surface of the body of revolution.

[0040] Thus, the two bodies 10 and 11 may each have 25 a conical or more or less pronounced parabolic shape with a diameter increasing continuously from an apical end 13 towards the opposite end forming a base 14. In the above-mentioned mathematical expression this will correspond to a value of A equal or close to 1 and a 30 value of n in the range $1 \leq n \leq 2$. At their apices 13 the two bodies 10 and 11 are joined and connected by means of a flexible link 15 with an elastic occlusion membrane 16 made of an blood impermeable material. The membrane 16 has a diameter d_2 which is at least 35 equal to, but preferably greater than the diameter d_1 of the base of each body of revolution.

[0041] The blood impermeable elastic membrane 16 may be formed from a porous film or a non-woven fabric of e.g. polyurethane, polyethylene, polyamide or expanded PTFE.

[0042] In the same way as in the filter embodiment of 45 fig. 1 hook-like anchoring members 17 may be provided at base 14 of one or both of the bodies of revolution 10 and 11 to ensure reliable permanent fixing and localization of the occlusion device at a site of implantation.

[0043] As described above for the filter embodiment of fig. 1 the occluder embodiment in figs. 3 to 5 may be easily arranged in the distal end of an introduction catheter, not shown, having a fairly small external diameter 50 such as 2.5 mm and may be percutaneously introduced through the venous system or a puncture hole in a vessel segment. After introduction the occlusion device is ejected from the catheter and may completely obturate a vessel lumen due to the elastic membrane 16 which 55 is reliably retained at the site of implantation by the self-expansion of the two bodies of revolution 10 and 11 assisted by the pressure gradient from the blood the flow of which is instantly blocked by the occlusion of the ves-

sel.

[0044] Due to its flexibility and the general shape of the bodies of revolution as well as the cellular surface made up of wire members 12 the occlusion device is very flexible and suitable for introduction by means of an equally flexible conveying system whereby the risk of traumatization may be kept very low and the universality of the occlusion device for implantation in vessels of various diameters and geometry is ensured.

[0045] Instead of being joined together at their apices the two bodies of revolution 30 may as shown in fig. 6 have their apices somewhat separated and displaceably connected by a flexible axially extending wire member 31 to which the elastic blood impermeable membrane 32 is fixed. In the state of introduction, the bodies are turned inside out as shown in dotted lines to bring their apical ends into abutment with the membrane 32. After localization at the site of implantation this elastic deformation is reversed to cause the two bodies to be oriented with their bases facing each other and the elastic membrane.

[0046] With this modification the occlusion device may be suitable for closing of a so-called ASD-defect i. e. a defect in the atrial septum between the right and left atria. For this application, the conical or parabolic bodies of revolution may typically have a pronounced flat shape corresponding to values of A around 0,2 in the mathematical expression stated above.

[0047] Fig. 7 shows a different embodiment of an occlusion device specially intended for curing the fatal condition known as Patent Ductus Arteriosis (PDA) caused by a duct or flow passage between the pulmonary arteria and the aorta. In this embodiment, the device comprises only a single body of revolution 18 which as shown may be of a generally conical shape the apical end of which is connected through a flexible link with the elastic blood impermeable membrane 19 which in this case may be supported on its external side by an umbrella-like structure 20 of wire members.

[0048] Fig. 8 illustrates schematically the application of the two latter embodiments for closing, on one hand, an ASD 21 in the septum 22 between the right and left atria 23 and 24 and on the other hand a PDA 25 forming a duct between the bifurcation of the pulmonary arteria 26 and 27 and the aorta typically opposite the outlet to the subclavian arteria.

[0049] For the ASD closing is provided by means of the above described embodiment of the occluder device composed of two bodies 30 of a pronounced flat conical or parabolic shape with relatively large diameter base ends facing each other and the elastic membrane 32. Such a device may typically be introduced from the femoral vein through the lower caval vein 33 opening into the right atrium.

[0050] For the PDA closing is provided by means of a single body device 34 as exemplified by the embodiment of fig. 7 which may likewise be introduced through the femoral and lower caval veins.

[0051] Thus, by means of the medical article of the invention ASD and PDA defects may be cured without any need of open-heart surgery and with a considerably simpler delivery system and procedure than available in the prior art.

[0052] Fig. 9 shows an embodiment specifically designed for permanent complete occlusion of a part of the venous system comprising a matricular vein section to which smaller branch veins are connected in a bifurcation or trifurcation. In its general configuration the medical article may correspond to the embodiment of figs. 3 to 5 with the modification that an injection catheter 39 extends axially through the two bodies of revolution 40 and 41 and the elastic membrane 42 which is constructed to provide sealing around the catheter 39 and also seal-off the axial passage for the catheter after removal of the latter.

[0053] By implantation of the medical article of fig. 9 in the matricular section of the vein complete occlusion will be provided for the downstream section thereof with which the branch veins communicate. By means of the catheter 39 it is now possible to inject an agent such as alcohol which will provide occlusion of the branch veins in the same operation.

[0054] As an example fig. 10 illustrates application of the embodiment of fig. 9 to the treatment of varicocele associated with the therapy of male infertility by occlusion the infrainguinal segment 43 of the spermatic vein 44 communicating in its lower end with the complex venous drainage system of the scrotum including the pampiniform plexus and the testicular veins as schematically exemplified by the vein group 45-47 joining segment 43 in a trifurcation. In its upper part the spermatic vein 44 communicates through the renal vein 49 with the lower caval vein 50.

[0055] As shown in fig. 10 the article of fig. 9 may be implanted at the level of the superficial inguinal ring 48 and after proper localization and implantation an injection of alcohol typically in an amount of about 3 ml may be administered through catheter 39 to the infrainguinal segment 43 to occlude the branch veins 45 to 47.

[0056] Whereas various embodiments of the medical article of the invention have been described hereinbefore these examples and the medical applications associated therewith should not be considered exhaustive. The invention opens for a wide range of modifications and further developments for treatment of a diversity of defects in the human vascular system within the scope of the following claims.

50

Claims

1. A medical filter for intravenous implantation into a patient for the capture of thrombi, comprising a self expanding body shaped substantially into the form of a body of revolution, the surface of which is defined by wire members forming cells of a generally

polygonal shape over at least a part of said surface, characterized in that said body of revolution (1, 2; 10, 11; 18; 30) has a diameter increasing continuously in an axial direction of the body from one end forming an apex (4, 13) towards the opposite end forming a base (5, 14).

2. A medical filter as claimed in claim 1, characterized in that said body of revolution (1, 2; 10, 11; 18; 30) is defined by a generatrix (6) forming a n-th order curve according to the formula

$$y = A \cdot x^n$$

where for a given point on the surface of the body x is the radius in the radial plane including said point, y is the distance from said radial plane to a plane parallel thereto including the geometrical apex, A is a constant and $n \geq 1$.

3. A medical filter as claimed in claim 1 or 2, characterized in that said cells are of a general rhombic shape.
4. A medical filter as claimed in claim 1, 2 or 3, characterized in that anchoring members (7, 17) for fixing the article to vascular walls is provided at the circumference of said base.
5. A medical filter as claimed in any of the preceding claims, characterized in that it is provided with wire members (8) extending substantially diametrically across said base and being connected with each other at the centre to function as extraction members.
6. A medical filter as claimed in any of the preceding claims, characterized in that it comprises two bodies of revolution (1, 2; 10, 11; 30) connected at their apices (4, 13).
7. A medical article as claimed in claim 2 and any of claim 3 to 6, characterized in that said body or bodies of revolution (1, 4; 10, 11; 18; 30) is of a generally parabolic shape with

$$1 < n \leq 2.$$

8. A medical occlusion device for implantation into the vascular system of a patient for closing a vessel lumen or defects in a vascular wall, comprising a self expanding body shaped substantially into the form of a body of revolution, the surface of which is defined by wire members forming cells of a generally polygonal shape over at least a part of the said surface, characterized in that said body of revolution

(1, 2; 10, 11; 18; 30) has a diameter increasing continuously in an axial direction of the body from one end forming an apex (4, 13) towards the opposite end forming a base (5, 14), and that a separate relatively flat disc or umbrella shaped, elastic membrane (16, 19, 32) of a blood impermeable material is connected with said one end of said body of revolution (10, 11; 18; 30) and is coaxially therewith, said membrane (16, 19, 32) having a diameter (d_2) exceeding the maximal diameter (d_1) at the base of 'said body.'

9. A medical occlusion device as claimed in claim 8, characterized in that said body of revolution (1, 2; 10, 11; 18; 30) is defined by a generatrix (6) forming a n-th order curve according to formula

$$y = A \cdot x^n$$

where for a given point on the surface of the body x is the radius in the radial plane including said point, y is the distance from said radial plane to a plane parallel thereto including the geometrical apex, A is a constant and $n \geq 1$.

10. A medical occlusion device as claimed in claim 8 or 9, characterized in that said cells are of a generally rhombic shape.

11. A medical occlusion device as claimed in claim 8, 9 or 10, characterized in that said membrane (7, 17) of fixing the article to vascular walls is provided at the circumference os said base.

12. A medical occlusion device as claimed in any of claims 8 to 11, characterized in that it comprises two bodies of revolution (1, 2; 10, 11; 30) connected at their apices (4, 13).

13. A medical occlusion device as claimed in claim 9 and any of claims 10 to 12, characterized in that said body or bodies of revolution (1, 4; 10, 11; 18; 30) is of a generally parabolic shape with $1 < n \leq 2$.

14. A medical occlusion device as claimed in claim 8, characterized in that said membrane (16, 19, 32) is connected with the apical end (4, 13) of said body revolution (10, 11; 18; 30).

15. A medical occlusion device as claimed in claim 8 or 9, characterized in that said cells are of a generally pentagonal or hexagonal shape.

16. A medical occlusion device as claimed in any of claims 8 to 15, characterized in that said membrane (16, 19, 32) is connected with said body or bodies of revolution (10, 11; 18; 30) through a flex-

ible link (15).

- 17.** A medical occlusion device as claimed in any of claims 8 to 16, characterized in that said membrane (16, 19, 32) is formed from a porous film or non-woven fabric of polyurethane, polyamide or PTFE.
 - 18.** A medical occlusion device as claimed in any of claims 8 to 14, 16 and 17, characterized in that it comprises a single body of revolution (18) connected at its apical end with an umbrella-link supporting structure (20) for said membrane (19).
 - 19.** A medical occlusion device as claimed in claim 18, characterized in that said membrane (16, 32) is arranged between said bodies (10, 11; 30).
 - 20.** A medical occlusion device as claimed in claim 19, characterized in that said two bodies of revolution (30) have their apical ends axially separated and connected by a flexible wire member (31) to which said membrane (32) is fixed.
 - 21.** A medical occlusion device as claimed in claim 19, characterized in that an injection catheter (39) is arranged to extend substantiably axially through said bodies of revolution (40, 41).

Patentansprüche

1. Medizinischer Filter für die intravenöse Implantation in einen Patienten zur Erfassung von Thromben, umfassend einen selbst-expandierenden Körper, der im wesentlichen die Form eines Rotationskörpers aufweist; dessen Oberfläche durch Drahtelemente begrenzt ist, die Zellen einer im allgemeinen polygonalen Form über zumindest einen Teil der Oberfläche bilden, dadurch gekennzeichnet, dass der Rotationskörper (1, 2, 10, 11, 18, 30) einen Durchmesser aufweist, der in axialer Richtung des Körpers von einem einen Scheitel (4, 13) bildenden Ende gegen das gegenüberliegende, eine Basis (5, 14) bildende Ende kontinuierlich zunimmt.
 2. Medizinischer Filter nach Anspruch 1, dadurch gekennzeichnet, dass der Rotationskörper (1, 2, 10, 11, 18, 30) von einer Generatrix (6) begrenzt wird, die eine Kurve n-ter Ordnung nach der Formel

$$y = A \cdot x^n$$

bildet, wobei für einen gegebenen Punkt auf der Oberfläche des Körpers x der Radius in der radialen Ebene einschließlich dieses Punktes ist, y die Distanz von der radialen Ebene zu einer dazu paral-

Ielen Ebene einschließlich des geometrischen Scheitels ist. A eine Konstante und $n \geq 1$ ist.

- 5 3. Medizinischer Filter nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Zellen eine im allgemeinen rhombische Form aufweisen.

10 4. Medizinischer Filter nach Anspruch 1, 2 oder 3, dadurch gekennzeichnet, dass am Außenumfang der Basis Verankerungselemente (7, 17) zur Befestigung des Artikels an Vaskulärwänden vorgesehen sind.

15 5. Medizinischer Filter nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass er mit Drahtelementen (8) versehen ist, die sich im wesentlichen diametral über die Basis erstrecken und in der Mitte miteinander verbunden sind, um als Extraktionselmente zu dienen.

20 6. Medizinischer Filter nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass er zwei Rotationskörper (1, 2; 10, 11; 30) umfasst, die an ihren Scheiteln (4, 13) verbunden sind.

25 7. Medizinischer Filter nach Anspruch 2 und einem der Ansprüche 3 bis 6, dadurch gekennzeichnet, dass der oder die Rotationskörper (1, 4; 10, 11; 18; 30) eine im allgemeinen parabolische Form mit $1 < n \leq 2$ aufweisen.

30 8. Medizinische Okklusionsvorrichtung zur Implantation in das Vaskulärsystem eines Patienten, um damit ein Gefäßlumen oder Defekte in einer Vaskulärwand zu schließen, welche einen selbstexpandierenden Körper umfasst, der im wesentlichen als Rotationskörper geformt wird und dessen Oberfläche von Drahtelementen begrenzt wird, die im wesentlichen polygonal geformte Zellen über mindestens einen Teil der Oberfläche bilden und welche dadurch gekennzeichnet ist, dass der Rotationskörper (1, 2; 10, 11; 18; 30) einen in axialer Richtung des Körpers von einem einen Scheitel (4, 13) bildenden Ende zum gegenüberlegenden, einer Basis (5, 14) bildenden Ende zunehmenden Durchmesser hat und dass eine getrennte, relativ flache Scheibe oder schirmartige, elastische Membran (16, 19, 32) aus blut-impermeablem Material mit dem einen Ende des Rotationskörpers (10, 11; 18; 30) verbunden und zu diesem koaxial angeordnet ist, wobei die Membran (16, 19, 32) einen Durchmesser (d_2) aufweist, der den maximalen Durchmesser (d_1) an der Basis des Körpers übertrifft.

35 9. Medizinische Okklusionsvorrichtung nach Anspruch 8, dadurch gekennzeichnet, dass der Rotationskörper (1, 2; 10, 11; 18; 30) durch eine Geometrix (6) definiert wird, die eine Kurve n-ten Gra-

des gemäß der Formel

$$y = Ax^n$$

bildet, wobei für einen gegebenen Punkt auf der Oberfläche des Körpers x der Radius in der radialen Ebene einschließlich dieses Punktes ist, y die Distanz von der radialen Ebene zu einer dazu parallelen Ebene einschließlich des geometrischen Scheitels ist, A eine Konstante und $n \geq 1$ ist.

10. Medizinische Okklusionsvorrichtung nach einem der Ansprüche 8 oder 9, dadurch gekennzeichnet, dass die Zellen eine im allgemeinen rhombische Form aufweisen.
11. Medizinische Okklusionsvorrichtung nach einem der Ansprüche 8, 9 oder 10, dadurch gekennzeichnet, dass die Membran (7, 17) zur Befestigung des Artikels an den Vaskulärwänden am Außenumfang der Basis vorgesehen ist.
12. Medizinische Okklusionsvorrichtung nach einem der Ansprüche 8 bis 11, dadurch gekennzeichnet, dass sie zwei Rotationskörper (1, 2; 10, 11; 30) umfasst, die an ihren Scheiteln (4, 13) verbunden sind.
13. Medizinische Okklusionsvorrichtung nach Anspruch 9 und einem der Ansprüche 10 bis 12, dadurch gekennzeichnet, dass der oder die Rotationskörper (1, 4; 10, 11; 18; 30) eine im allgemeinen parabolische Form mit $1 < n \leq 2$ aufweisen.
14. Medizinische Okklusionsvorrichtung nach Anspruch 8, dadurch gekennzeichnet, dass die Membran (16, 19, 32) mit dem Scheitelende (4, 13) des Rotationskörpers (10, 11; 18; 30) verbunden ist.
15. Medizinische Okklusionsvorrichtung nach Anspruch 8 oder 9, dadurch gekennzeichnet, dass die Zellen eine im allgemeinen pentagonale oder hexagonale Form aufweisen.
16. Medizinische Okklusionsvorrichtung nach einem der Ansprüche 8 bis 15, dadurch gekennzeichnet, dass die Membran (16, 19, 32) über ein flexibles Gelenk (15) mit dem oder den Rotationskörper(n) (10, 11; 18; 30) verbunden ist.
17. Medizinische Okklusionsvorrichtung nach einem der Ansprüche 8 bis 16, dadurch gekennzeichnet, dass die Membran (16, 19, 32) aus einem porösen Film oder aus Vliesstoff aus Polyurethan, Polyamid oder PTFE gebildet ist.
18. Medizinische Okklusionsvorrichtung nach einem der Ansprüche 8 bis 14, 16 und 17, dadurch ge-

kennzeichnet, dass sie einen einzigen Rotationskörper (18) umfasst, der an seinem Scheitelende mit einer schirmartigen Unterstützungsstruktur (20) für die Membran (19) verbunden ist.

- 5 19. Medizinische Okklusionsvorrichtung nach Anspruch 18, dadurch gekennzeichnet, dass die Membran (16, 32) zwischen den Körpern (10, 11; 30) angeordnet ist.
- 10 20. Medizinische Okklusionsvorrichtung nach Anspruch 19, dadurch gekennzeichnet, dass die beiden Rotationskörper (30) separate und durch ein flexibles Drahtelement (31), an dem die Membran (32) befestigt ist, verbundene Scheitelenden aufweisen.
- 15 21. Medizinische Okklusionsvorrichtung nach Anspruch 19, dadurch gekennzeichnet, dass ein Injektionskatheter (39) so angeordnet ist, dass er sich im wesentlichen axial durch die Rotationskörper (40, 41) erstreckt.

25 Revendications

- 30 1. Un filtre médical pour l'implantation intraveineuse chez un patient pour la capture de caillots, comprenant un corps auto-dilatable conformé essentiellement selon un corps de révolution dont la surface est définie par des éléments en fils formant des cellules d'une forme généralement polygonale sur au moins une partie de ladite surface, caractérisé en ce que ledit corps de révolution (1, 2, 10, 11, 18, 30) a un diamètre augmentant en continu dans une direction axiale du corps depuis une extrémité formant un sommet (4, 13) vers l'extrémité opposée formant une base (5, 14).
- 35 2. Un filtre médical selon la revendication 1, caractérisé en ce que ledit corps de révolution (1, 2, 10, 11, 18, 30) est défini par une génératrice (6) formant une courbe du n-ième ordre selon la formule

$$y = A \cdot x^n$$

où pour un point donné sur la surface du corps x est le rayon dans le plan radial comprenant ledit point, y est la distance depuis ledit plan radial jusqu'à un plan parallèle à celui-ci comprenant le sommet géométrique, A est une constante et $n \geq 1$.

- 45 3. Un filtre médical selon la revendication 1 ou 2, caractérisé en ce que lesdites cellules sont d'une forme générale en rhomboèdre.
- 50 4. Un filtre médical selon la revendication 1, 2 ou 3,

- caractérisé en ce que les moyens d'ancre (7, 17) pour fixer l'article aux parois vasculaires sont prévus à la circonférence de ladite base.**
5. Un filtre médical selon l'une quelconque des revendications précédentes, **caractérisé en ce qu'il est muni d'éléments en fils (8) s'étendant essentiellement diamétralement au niveau de ladite base et qui sont reliés les uns avec les autres au centre pour agir comme des éléments d'extraction.**
6. Un filtre médical selon l'une quelconque des revendications précédentes, **caractérisé en ce qu'il comprend deux corps de révolution (1, 2, 10, 11, 30) reliés à leurs sommets (4, 13).**
7. Un article médical selon la revendication 2 et l'une quelconque des revendications 3 à 6, **caractérisé en ce que ledit corps ou lesdits corps de révolution (1, 4, 10, 11, 18, 30) est (sont) d'une forme généralement parabolique avec $1 < n \leq 2$.**
8. Un dispositif d'occlusion médical pour l'implantation dans le système vasculaire d'un patient pour obtenir une lumière de vaisseaux ou des défauts dans une paroi vasculaire comprenant un corps autodilatable essentiellement conformé selon un corps de révolution, dont la surface est définie par des éléments en fils formant des cellules d'une forme généralement polygonale sur au moins une partie de ladite surface, **caractérisé en ce que ledit corps de révolution (1, 2, 10, 11, 18, 30) a un diamètre augmentant en continu dans une direction axiale du corps depuis une extrémité formant un sommet (4, 13) vers l'extrémité opposée formant une base (5, 14), et en ce qu'une membrane élastique en forme de parapluie ou de disque relativement plat séparé (16, 19, 32) d'un matériau imperméable au sang est reliée avec une extrémité dudit corps de révolution (10, 11, 18, 30) et est située coaxialement par rapport à celui-ci, ladite membrane (16, 19, 32) ayant un diamètre (d_2) dépassant le diamètre maximal (d_1) à la base dudit corps.**
9. Un dispositif d'occlusion médical selon la revendication 8, **caractérisé en ce que ledit corps de révolution (1, 2, 10, 11, 18, 30) est défini par une génératrice (6) formant une courbe du n-ième ordre selon la formule**
- $$y = A \cdot x^n$$
- où pour un point donné sur la surface du corps x est le rayon dans le plan radial comprenant ledit point, y est la distance à partir dudit plan radial jusqu'à un plan parallèle à celui-ci comprenant le sommet géométrique, A est une constante et $n \geq 1$.
10. Un dispositif d'occlusion médical selon la revendication 8 ou 9, **caractérisé en ce que lesdites cellules sont d'une forme générale en rhomboèdre.**
- 5 11. Un dispositif d'occlusion médical selon la revendication 8, 9 ou 10, **caractérisé en ce que ladite membrane (7, 17) de fixation de l'article aux parois vasculaires est prévue à la circonférence de ladite base.**
- 10 12. Un dispositif d'occlusion médical selon l'une quelconque des revendications 8 à 11, **caractérisé en ce qu'il comprend deux corps de révolution (1, 2, 10, 11, 30) reliés à leurs sommets (4, 13).**
- 15 13. Un dispositif d'occlusion médical selon la revendication 9 et l'une quelconque des revendications 10 à 12, **caractérisé en ce que ledit corps ou lesdits corps de révolution (1, 4, 10, 11, 18, 30) est d'une forme généralement parabolique avec $1 < n \leq 2$.**
- 20 14. Un dispositif d'occlusion médical selon la revendication 8, **caractérisé en ce que ladite membrane (16, 19, 32) est reliée à l'extrémité apicale (4, 13) dudit corps de révolution (10, 11, 18, 30).**
- 25 15. Un dispositif d'occlusion médical selon la revendication 8 ou 9, **caractérisé en ce que lesdites cellules sont d'une forme généralement pentagonale ou hexagonale.**
- 30 16. Un dispositif d'occlusion médical selon l'une quelconque des revendications 8 à 15, **caractérisé en ce que ladite membrane (16, 19, 32) est reliée audit corps ou auxdits corps de révolution (10, 11, 18, 30) par l'intermédiaire d'une liaison souple (15).**
- 35 17. Un dispositif d'occlusion médical selon l'une quelconque des revendications 8 à 16, **caractérisé en ce que ladite membrane (16, 19, 32) est formée à partir d'un film poreux ou d'un tissu non-tissé de polyuréthane, de polyamide ou de PTFE.**
- 40 18. Un dispositif d'occlusion médical selon l'une quelconque des revendications 8 à 14, 16 et 17, **caractérisé en ce qu'il comprend un seul corps de révolution (18) relié à son extrémité apicale avec une structure de support de liaison en parapluie (20) pour ladite membrane (19).**
- 45 19. Un dispositif d'occlusion médical selon la revendication 18, **caractérisé en ce que ladite membrane (16, 32) est agencée entre lesdits corps (10, 11, 30).**
- 50 20. Un dispositif d'occlusion médical selon la revendication 19, **caractérisé en ce que lesdits deux corps de révolution (30) ont leurs extrémités apicales séparées axialement et reliées par un élément en fil**

souple (31) auquel ladite membrane (32) est fixée.

- 21. Un dispositif d'occlusion médical selon la revendication 19, caractérisé en ce qu'un cathéter d'injection (39) est agencé pour s'étendre essentiellement axialement au travers desdits corps de révolution (40, 41).**

10

15

20

25

30

35

40

45

50

55

10

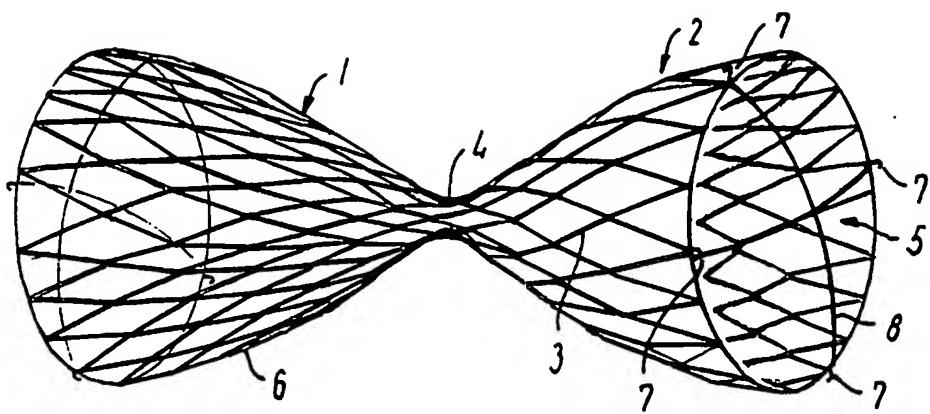


FIG. 1

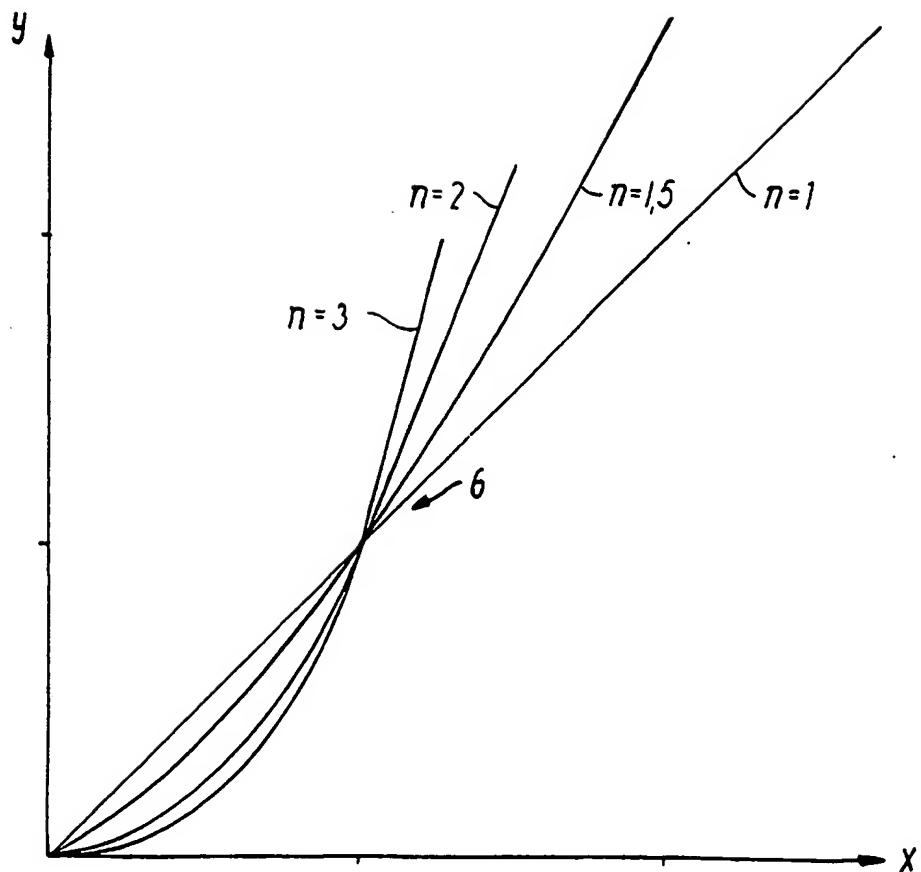


FIG. 2

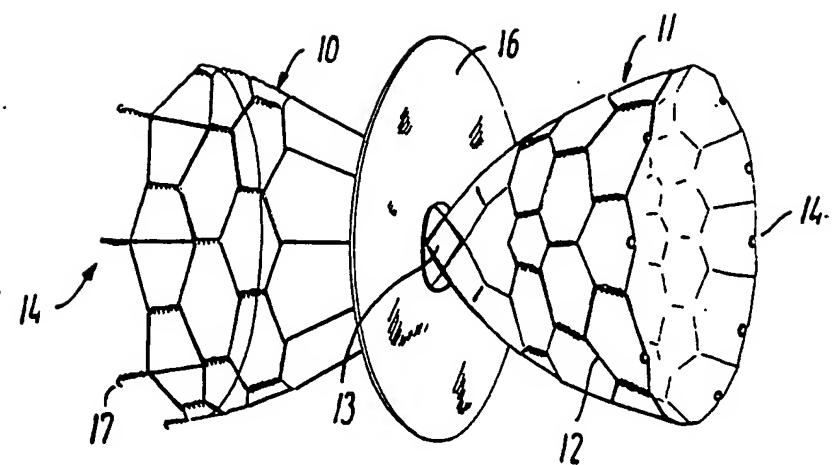


FIG. 3

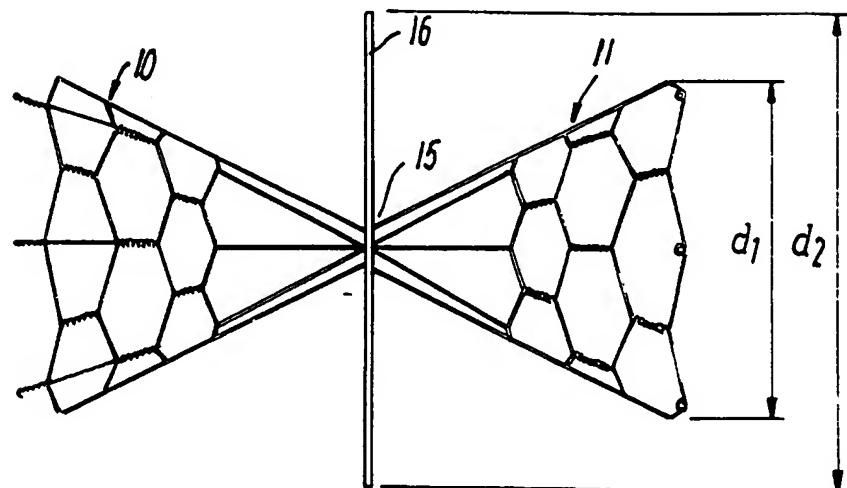


FIG. 4

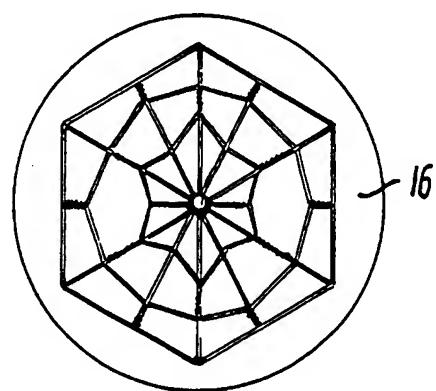
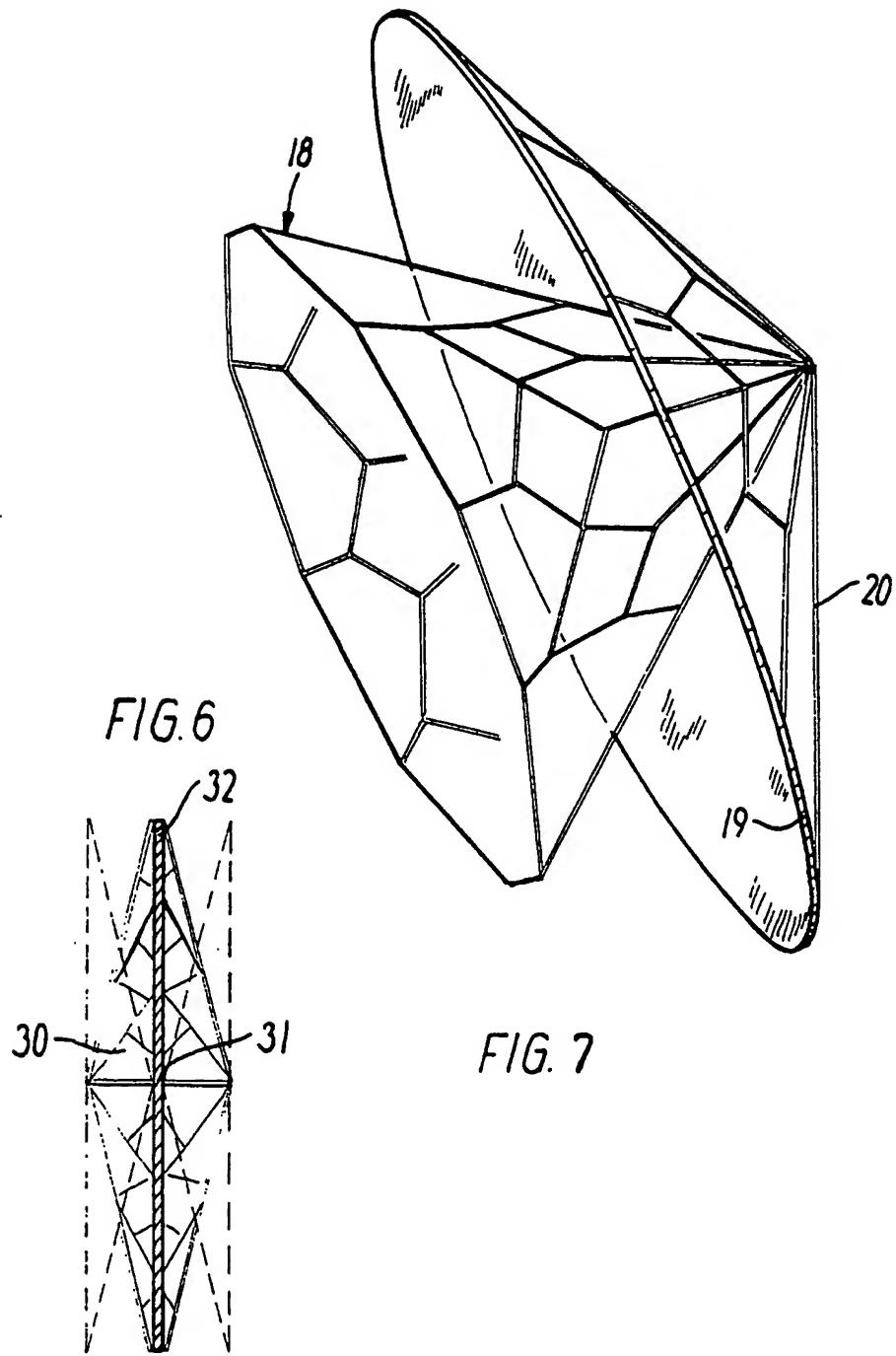


FIG. 5



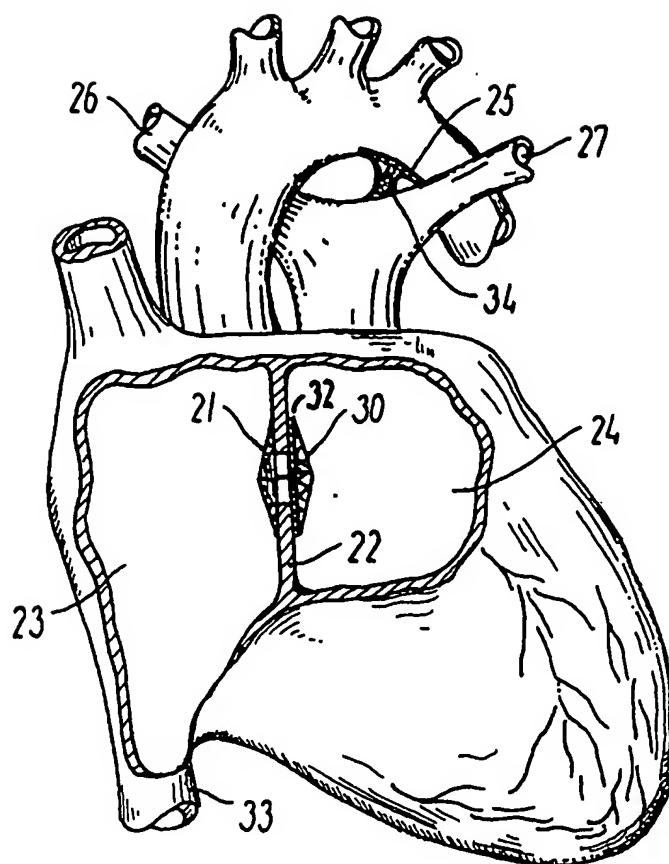


FIG. 8

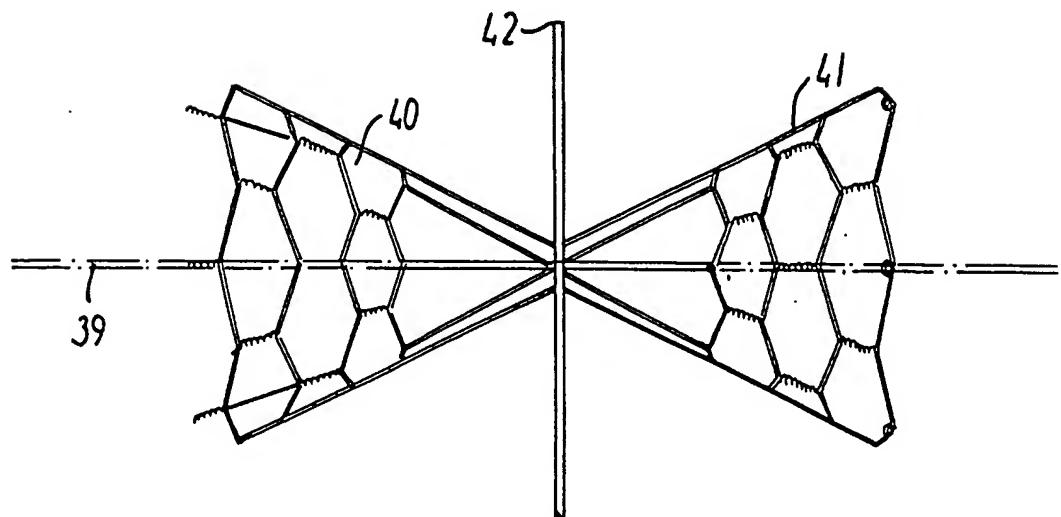


FIG. 9

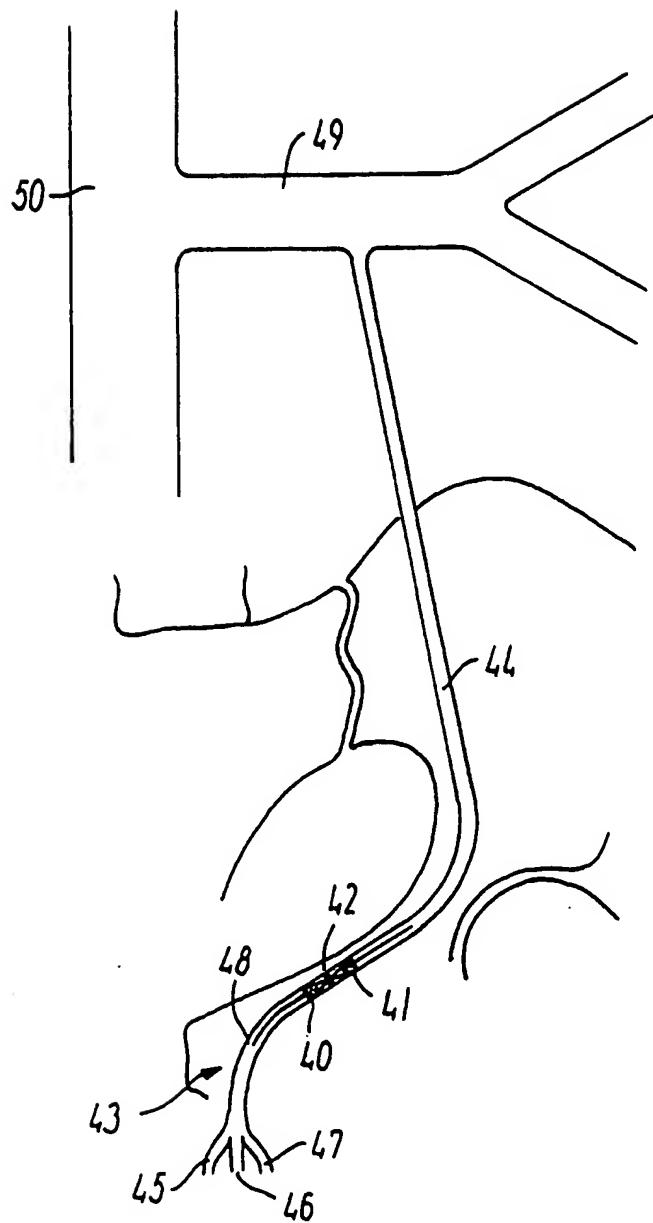


FIG. 10

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.